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CathPCI Registry®

Program Overview

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1. Background

Coronary heart disease (CHD) leads to serious health complications, including myocardial infarction (MI) and cardiac death, and is the leading cause of death among Americans. CHD caused over 450,000 deaths in 2004, or one of every five deaths in the United States. In that same year, the prevalence of coronary heart disease for adults aged 20 and older has been estimated at over 15.8 million.[1]

CHD results when there is a build up of fatty material and plaque within the coronary arteries, which then limits and restricts the flow of blood to the heart. Because the heart muscle is not receiving a sufficient supply of blood, this can lead to myocardial ischemia (MI), also known as angina. The term "acute coronary syndrome" (ACS) refers to several clinical conditions that arise as a result of acute myocardial ischemia, including ST-segment elevation myocardial infarction (STEMI), non-ST segment elevation myocardial infarction (NSTEMI), and unstable angina (UA).[2] Chronic stable angina refers to a predictable pattern of symptoms, usually with exercise.

CHD has a tremendous impact not only on the health and well-being of Americans, but also on healthcare systems. In 1997, there were over five million visits to U.S. emergency departments for the evaluation of chest pain and related symptoms.[3] In 1996, the National Center for Health Statistics reported 1,433,000 hospitalizations for UA or NSTEMI. Applying the conservative estimate of 30% of MI patients who have STEMI from the National Registry of Myocardial Infarction [NRMI-4], approximately 400,000 STEMI events occur per year in the U.S.[4] Additionally, the estimated incidence of all myocardial infarction (MI) is 865,000 attacks annually. The risk of further cardiac disease complications, such as another heart attack, sudden death, angina pectoris, heart failure and stroke for those who survive an MI is substantial.[5]

Although many patients with CHD can be successfully managed with medications, there are many situations where it is necessary to restore blood flow to the coronary artery and heart muscle by either coronary artery bypass surgery (CABG) or by percutaneous coronary intervention (PCI). PCIs are performed to reduce the blockage and thus return normal blood flow, whereas CABG uses an artery or vein to bypass the diseased artery. PCIs are the second most common procedure in catheterization labs, with an estimated 664,000 PCI procedures performed on 658,000 patients in 2004 in the United States. In fact, from 1987–2004, the number of procedures increased 326 percent.[6]

Coronary angioplasty was first introduced by Andreas Gruentzig in 1977 as a non-surgical method for coronary arterial revascularization.[7] With experience and time, the cognitive and technical aspects, as much as the equipment used to perform angioplasty, became more refined. PCI is now more commonly performed than CABG surgery. The results of clinical trials have clarified the utility of angioplasty in terms of effectiveness, complications, and patient selection. Advances in coronary-based interventions, especially the use of bare-metal stents (BMS) and drug-eluting stents (DES), have improved the efficacy and safety of percutaneous revascularization for patients undergoing percutaneous transluminal coronary angioplasty (PTCA). Additional benefits of this procedure include reduced recovery time and patient discomfort.[8]

Fortunately, the numbers of deaths due to CHD have been declining for most of the last century. In the period from 1994–2004, for example, the number of deaths declined by 18 percent.[9] It is arguable that this decline is directly related to advancements in technology, spurring the growth of life-saving procedures conducted in the cardiac catheterization laboratory. Improvements in the quality of imaging equipment, the introduction of new potent anti-platelet agents that reduce the likelihood of thrombotic complications, and advancements in coronary stent technology have resulted in a high level of patient safety and very low mortality and adverse clinical event rates.[10]

Percutaneous coronary interventions typically involve the use of balloon dilation or angioplasty with or without stenting. The procedure is specifically used to treat stable and unstable angina, and acute MI.[11] PCI may also be indicated as an elective procedure for patients whose symptoms remain despite treatment. During the early practice of balloon angiography, complications included dissection, abrupt closure, and restenosis (renarrowing of the treated lesion). With the advent of coronary stents in the early 1990s, the first two problems have been largely controlled. Current NCDR® data shows that stents are used in about 80 percent of all PCI procedures.[12] Outcomes data from the same source support the trial data that indicate that stents improve the short-term success rate and the safety of PCI.

The outcomes of PCI are related to the mechanisms of the employed devices as well as clinical and anatomic patient-related factors. Complications have been categorized as major (death, MI, and stroke) or minor (transient ischemic attack, access site complications, renal insufficiency, or adverse reactions to radiographic contrast). Additional specific complications include intracoronary thrombosis, coronary perforation, tamponade, and arrhythmias.[13] Analyses of large registries indicate overall unadjusted in-hospital death rates at 0.4% to 1.9%.[14] Rates of periprocedural MI have ranged from 0.4% to 4.9%. Using a consistent definition for MI, the incidence of this complication has declined by approximately 50% with the routine use of intracoronary stents.[15]

Restenosis remains an issue for patients treated with conventional balloon angioplasty. However, compared with conventional balloon angioplasty, the use of BMS has been shown to reduce the frequency of restenosis by 30% to 50% and ultimately, the need for repeat revascularization.[17] Still, of all the patients who undergo PCI, it's estimated that 17% to 32% of patients receiving BMS will develop restenosis.[16] Depending on the pattern of in-stent restenosis, treatment with balloon angioplasty alone is still followed by a further restenosis in 45% to 55% of cases.[18] Intravascular brachytherapy has been used in recent years to treat in-stent restenosis, but late recurrence remains frequent.[19]

Drug-eluting stents have taken stent technology a step farther by further reducing the occurrence of restenosis after treatment by both holding open the vessel and releasing a drug that combats the renarrowing of the artery. In clinical trials, DES procedures have been shown to reduce restenosis rates to the single digits. Recent data, however, indicate the possibility of a small additional risk of late thrombosis within the DES, especially in more complex lesions and patient populations.[20] This is currently the subject of intense research to determine the exact incidence and cause of this problem. Therefore, caution must be exercised, and the decision to use drug-eluting stents must take into account the potential risks and benefits unique to each individual. Research continues into better pharmacological and device therapies to safely minimize the chances of restenosis.

Over the past 20 years, the cardiac catheterization laboratory, often described as the "cornerstone of the delivery system for many cardiovascular procedures performed in the US," has advanced from a simple radiographic imaging facility into a multi-purpose diagnostic and therapeutic laboratory where patients suffering from a spectrum of coronary artery, valvular, and congenital heart disease can be evaluated thoroughly and treated.[21] The traditional laboratory located within the hospital and providing on-site cardiac surgical support now extends to labs located within community hospitals without on-site surgical support, to mobile laboratories dedicated to outpatient services either physically annexed to a hospital with or without surgical support, and, finally, to those in freestanding lab environments. Continued advancements in the diagnosis and treatment of CHD will contribute to a successful reduction in the morbidity and mortality of these patients. Efforts are ongoing to identify which patient populations are better served having their diagnostic and/or therapeutic procedures performed at some of these less "traditional" facilities.

2. CathPCI Registry Description

The CathPCI Registry is a national, risk-adjusted, outcomes-based quality improvement program. It was the first in a suite of cardiovascular registries under the auspices of NCDR (National Cardiovascular Data Registry), whose goal is to be the largest, most comprehensive national cardiovascular patient data repository ever developed. The CathPCI Registry measures outcomes of patients undergoing diagnostic catheterizations and percutaneous coronary interventions (PCIs). By participating in the CathPCI Registry, enrolled hospitals and cath labs can measure their performance in diagnosing and treating these patients against similar comparison groups and national benchmarks.

The purpose, objectives, audience, and scope of the CathPCI Registry are far-reaching.

3. Purpose of the CathPCI Registry

- Create a national surveillance system to assess the characteristics, treatments, and outcomes of patients with coronary heart disease who undergo procedures in cardiac catheterization laboratories, including those treated with PCI
- Optimize the outcomes and management of coronary heart disease patients through implementation of evidence-based guideline recommendations in clinical practice
- Facilitate efforts to improve the quality and safety of coronary heart disease care and investigate novel quality improvement methods
- Provide a risk-adjusted assessment of patients for comparison

4. Objectives of the CathPCI Registry

- Improve adherence to the ACC/AHA PCI, STEMI, and NSTEMI guidelines recommendations through monitoring of process of care measures, development of quality indicators based upon guidelines recommendations, and benchmarked quality of care feedback reports
- Improve adherence to other ACC/AHA guidelines where applicable, including the Appropriate Use Criteria for Coronary Revascularization.
- Explore the association between evidence-based acute treatment strategies and risk-adjusted clinical outcomes
- Assess utilization of diagnostic imaging, laboratory tests and invasive procedures; and track hospital length of stay data
- Assess utilization of evidence-based discharge medications and risk factor modification interventions
- Identify barriers to implementing guideline recommendations for patients with coronary heart disease, and develop effective strategies to overcome these barriers
- Provide a valuable resource for research designed to improve the treatment and outcomes patients with coronary heart disease
- Educate participating sites on the gathering, submission and evaluation of data submitted to the CathPCI Registry.
- Facilitate data collection for use in JCAHO core measures reporting requirements and for other performance measures
- Provide a useful reporting tool for hospitals to analyze, report, and improve quality of patient care at a local level

Sample questions the CathPCI Registry can answer

- What is the prevalence of treatments used to treat coronary heart disease patients in the cardiac catheterization laboratory?
- What are the procedures that are being used and how do they relate to outcomes?
- What coronary devices are being used and how do they relate to outcomes?

- What are the rates of in-hospital procedure-related complications?
- How do measures of quality of care (i.e., use of proven therapies) relate to clinical outcomes?

5. CathPCI Registry Audience

Clinicians (cardiologists, emergency medicine physicians, hospitalists, primary care physicians, nurses, physician assistants, nurse practitioners), pharmacists, case managers, allied health care personnel, hospital quality improvement personnel and administrators, professional organizations, accrediting organizations, regulatory agencies, payers, pharmaceutical and device industry, and clinical research organizations.

6. How to Participate in the CathPCI Registry

First steps include registering at the NCDR CathPCI Registry Website, **www.ncdr.com/cathpci**. A CathPCI Registry Support Specialist will contact you after registration with the forms you'll need to complete your enrollment, including the Business Associate Agreement.

7. CathPCI Registry Case Inclusion Criteria

Adult patients who have attained the age of 18, based on admission date to the hospital, and who undergo a diagnostic cardiac catheterization (passing a catheter into the aortic root for pressure measurements and/or angiography, and can include LV pressure measurements, LV angiography, coronary angiography, and coronary artery bypass angiography) and/or PCI (passage or attempted passage of a coronary device across one or more coronary lesions for purposes of increasing the intraluminal diameter of the vessel and/or to restore or improve circulation).

8. CathPCI Registry Data Collection

NCDR registry products, including the CathPCI Registry, are created under the leadership of clinical experts with critical input from NCDR participants regarding the feasibility of implementation and the burden of data collection. The CathPCI Registry collects data on a number of variables, including the areas of administrative, demographic, admission status, history and risk factors, cardiac status, cath lab visits for both diagnostic and PCI information, lesion and treatment information, adverse events, and discharge status. Data are collected, validated, and submitted under the responsibility of a designated Registry Site Manager at each participating institution.

8.1 Complimentary Web-Based Data Entry Tool

Information collected on Data Collection Forms (DCFs) may be entered by participating facilities via a secure, password-protected Website managed by NCDR. Participation in the CathPCI Registry is required to be able to enter and access data.

8.2 Vendor-Based Data Capture

The CathPCI Registry has contracted with a variety of software vendors that offer a large range of catheterization laboratory products. NCDR reviews and certifies each software application prior to its distribution to verify it meets the strict data collection standards and export requirements as defined by NCDR. Since many of the vendors' software applications do much more than collect and export CathPCI Registry data, participants should consider their own software requirements when reviewing vendor product information. NCDR provides a brief description of each vendor as well as a summary of their product information at http://www.ncdr.com/WebNCDR/CERTIFIEDVENDORS.ASPX .

9. Collection of Existing Recorded Data, Privacy, and Ethical Considerations

The American College of Cardiology Foundation (ACCF) does not require Institution Review Board review and approval as a condition of participation in NCDR. However, the ACCF does require that all participating facilities abide by the policies and procedures of their facility. Please consult with your facility for guidance in participation in quality improvement activities. This program summary for the registry may be used for presentation to your IRB if required by your facility policies.

Registry data is collected based on the registry specific inclusion criteria. Data collected in the registry are collected using existing medical record data. The registry does not require participating facilities to contact individual patients.

The ACCF takes reasonable safeguards to protect the data collected through the registry including physical, technical and administration safeguards required of a Business Associate under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) as amended by the HITECH ACT. All facilities participating in the registry are required to sign a Business Associate Agreement with the ACCF which stipulates permitted and restricted data uses.

The registry requires collection of direct identifiers allowing data captured in multiple registries to be interoperable, hence reducing the data collection burden of participating facilities. The Business Associate Agreement also stipulates permitted disclosures and secondary uses of registry data. Please note that the ACCF is only permitted to disclose a Limited Data Set to third parties for very restrictive purposes. The only permitted disclosure of direct identifiers is to entities who actively act as sub-contractors of the ACCF. Such sub-contractors are bound by contract under the same requirements stipulated in the Business Associate Agreement as required by HIPAA. Additionally, ACCF may release data to entities where a Participant has authorized the release of such information.

10. CathPCI Registry Data Quality

The NCDR Data Quality Program (DQP) is designed to meet the requirements needed for a comprehensive health information management system. The Onsite Data Audit Program is a component of this effort. The overall purpose of the DQP is to ensure that data submitted to NCDR are complete, consistent, and accurate - ultimately improving the overall quality of the CathPCI Registry.

10.1 Data Completeness

In keeping with established NCDR data quality procedures, participant data submissions are reviewed to establish overall completeness prior to analyzing and developing reports for any given quarter. The Data Quality Report (DQR) process assesses the overall completeness of a participant's data submission and provides feedback to the participating hospitals. The DQR provides participants with a confidential analysis of their data completeness, and is used by the participant to help prioritize data "cleaning" efforts.

10.2 Data Consistency and Accuracy

The NCDR is implementing a new strategy, the Data Quality Program, to improve the data reported to each registry. The DQR and special analyses of the data are parts of the Program. Another part is the auditing of data, with results used for instructing participants on how to improve data submitted. Each year, participating sites are randomly selected to be audited. Trained nurse abstractors conduct medical record reviews and blind data abstraction of randomly selected patient medical records at each site. Audit results are analyzed for overall accuracy by comparing audit findings against data originally submitted from each site. Each participant receives a confidential audit report which displays their audit score and individual accuracy for each data element.

11. CathPCI Registry Call for Data, Reporting, and Data Analysis

The quarterly Call for Data (CFD) occurs during the calendar month following the end of each quarter, i.e., April, July, October, and January. Data files are uploaded via a secure Website. Once data are submitted, DQR that identifies invalid data to be fixed and resubmitted is available to participants on the NCDR Website within a short period of time after submission of the data file. This allows for minimal revision volumes and provides rapid cycle feedback on the data submission process. After submission/resubmission, the data is compiled and analyzed for the CathPCI Registry quarterly benchmark report.

CathPCI Registry participants receive comprehensive, timely information about measuring quality of care for their CHD patients in the form of quarterly and annual comparative benchmark reports. These institution-specific reports are comprised of evidence-based elements that correspond to the CathPCI Registry data elements, facilitating continuous monitoring of quality improvement efforts and enabling facilities to compare, on a blinded basis, their institution's practice patterns to national averages and volume-based peer comparison groups. Participants can use this information to reduce complications in cardiac catheterization and PCI procedures, improve patient care, support local quality-improvement programs, and satisfy the requirements of regulatory and contracting organizations.

With over nine million cardiac catheterization and PCI records, the CathPCI Registry is a potent research tool that permits focused analysis of clinical treatments, procedures, and outcomes of patients diagnosed with coronary heart disease who are treated with catheterization or PCI procedures. Data collected through the CathPCI Registry can be analyzed to assess compliance with clinical guideline recommendations, to assist in medical decision-making, and to assess the appropriateness of medical care provided for patients with CHD.

12. Using CathPCI Registry Data for American Board of Internal Medicine (ABIM) Recertification

All physicians who are board-certified and have a time-limited certification must complete a Maintenance of Certification (MOC) process to renew their certification. ABIM-certified physicians have 10 years to complete the process, which includes self evaluation of practice performance. NCDR CathPCI Registry data can be used to earn up to 80 points out of the 100-point total required by ABIM. This practice performance requirement is referred to as MOC Part IV. Visit **www.cardiosource/moc** for more information.

There are several Web-based tools offered by ABIM to complete MOC Part IV called Practice Improvement Modules (PIMs). The ABIM self-directed PIM allows physicians to use ABIM-approved data sources to complete the module. The NCDR is an approved data source for completing the ABIM self-directed PIM for physicians whose patient records are submitted to the CathPCI Registry. Completion of the ABIM self-directed PIM is also recognized by a number of insurance companies and Pay for Performance programs. For more information, visit **http://www.abim.org/moc/healthcare/healthplans/default.aspx**.

13. Ongoing CathPCI Registry Participant Support

The CathPCI Registry provides "help desk" support to all participants from 9 am to 5 pm (ET) on regular business weekdays. This includes telephone and email support for participants who have questions or need assistance with any facet of the registry operations.

13.1 Participant Training and Orientation

Training and orientation are critical functions to ensure data quality and, ultimately, a high-quality registry. In addition to the "help desk" functions described above, training and orientation take the following forms:

- ***Introductory Calls and Webcasts***

  CathPCI Registry participants are invited on a routine basis to join calls and/or Webcasts where registry staff provide an overview to the CathPCI Registry program and answer questions.

- ***Electronic Data Capture Training***

  Participants who submit data via the NCDR Web-based Data Entry Tool will need to complete training for the system, either via Webcast or online module. This training educates users regarding platform functionality, including data entry and review, and user account management.

13.2 Regional Group Meetings

NCDR registry participants, in many cases, have organized themselves into regional training and networking groups. CathPCI Registry staff may support these groups and also assist with the organization of additional groups as needed. Educational meetings and/or teleconferences may include presentations regarding recent findings from CathPCI Registry data analyses, strategies for ensuring successful collaboration between various hospital specialties and departments in support of the quality improvement process, question and answer sessions or case studies, and other topics of interest.

14. CathPCI Registry Governance

The mission of NCDR is to improve the quality of cardiovascular patient care by providing information, knowledge, and tools; implementing quality initiatives; and supporting research that improves patient care and outcomes. Oversight of NCDR is provided by the NCDR Management Board.

14.1 CathPCI Registry Steering Committee

The CathPCI Registry Steering Committee reports to the NCDR Management Board. It provides strategic direction for the CathPCI Registry and monitors research and clinical activities to include the following:

- Set a high-level agenda for the strategic direction of the CathPCI Registry
- Advocate, promote, and influence key groups regarding CathPCI Registry activities
- Assure that activities conducted by the CathPCI Registry Research and Publications Committee and Clinical Support Team are congruent with NCDR methodologies and policies
- Identify new opportunities and strategies to further promote utilization of the CathPCI Registry
- Establish working groups as needed to support specific projects

14.2 CathPCI Registry Research and Publications Committee

This committee oversees all activities related to research and publications for the CathPCI Registry, including:

- Overseeing all research activities, including the evaluation, improvement, approval, and prioritization of investigator-initiated as well as industry and government research proposals
- Overseeing the production of analytical and/or descriptive abstracts, poster presentations, and manuscripts
- Selecting secondary reviewers for abstract and manuscript development
- Participating in open sessions of the Data Monitoring Committee and reviewing reports from closed sessions

14.3 CathPCI Registry Clinical Support Team

The CathPCI Registry Clinical Support Team provides ad hoc clinical expertise as needed to respond to questions from participating hospitals regarding data elements and data collection. The team consists of a small group of members, all of whom are clinical experts on the CathPCI Registry patient population.

15. CathPCI Registry Operations Oversight

NCDR oversees all activities associated with the CathPCI Registry, including the NCDR Information Technology and Research and Innovation departments that provide all technology management, data coordinating, report generation, and statistical functions for the CathPCI Registry.

16. CathPCI Registry Sponsorship

There is no outside funding for the CathPCI Registry.

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